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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,107	10/14/1999	PETER KUFER	3816-4000	6846

7590 03/28/2002

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345 PARK AVENUE  
NEW YORK, NY 10154

EXAMINER
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ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

19

## Office Action Summary

Applicati n No.

09/403,107

Applicant(s)

KUFER ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/27/01, 12/6/01 and 1/31/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22,26-29,31,32 and 34-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22,26-29,31,32 and 34-64 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology 1600.

2. Applicant's amendments, filed on 10/14/99, 1/3/01, 4/24/01, 5/22/01, 8/20/01, 11/27/01, 12/6/01 and 1/31/02 (Paper Nos. 6, 7, 11-12, 14 and 16-18), are acknowledged.

Claims 23-25, 30 and 33 have been cancelled.

Claims 34-64 have been added.

Claims 1, 3, 5-14, 16-22, 26, 28-29, 31-33, 34, 36 and 50-52 have been amended.

*Claims 1-22, 26-29, 31-32 and 34-64 are pending and being acted upon presently*

### *Sequence Compliance*

3. Sequence compliance: The CRF, paper copy of the Sequence Listing and Statement that the CRF and Sequence Listing are identical, filed 1/3/01, has been found acceptable and entered.

However,

4. The specification is objected to under 37 CFR 1.821(d) because the SEQ ID NOS are not disclosed in the specification adjacent referenced sequences (for example, claim 32 and in the Figure and/or Brief Description of Figures 6-9). Appropriate correction is required.

### *Election/Restriction*

5. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is rendered moot in view of the new Requirement set forth below. The previous Restriction set forth in Paper No. 9 is hereby vacated.

6. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-17, drawn to method for the production of an anti-human antigen receptor comprising the step of selecting a VH chain which is derived from essentially unprimed mature human B lymphocytes.

Group II, claims 18-22, 28-29, 31-32 and 34-64, drawn to anti-human antigen receptors and pharmaceutical compositions comprising the same.

Group III, claims 26-27, drawn to a kit comprising a rearranged VH and VL immunoglobulin chains wherein at least one of the VH and VL chains is derived from essentially unprimed mature human B lymphocytes.

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### ***Species Election***

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A) a particular series of method steps identifying the nature of the "selecting step" (e.g., that set forth in claim 10 versus that set forth in claim 13) and whether the method of claim 1 further comprises the step set forth in claim 11 and/or the step set forth in claim 14 and/or the step set forth in claim 16;

B) a particular epitope defined by at least one amino acid sequence set forth in claim 31;

C) an ultimate sequence composition the VH and VL or the at least one CDR of the VH and VL of the anti-human antigen receptor of Group II.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

For Species A, claim 1 is generic to the various combination of method steps set forth in claims 10-17;

For Species B, claim 31 sets forth the particular epitope sequence(s) and no claim is generic;

For Species C, claim 32 sets forth the individual VH and VL sequences and claim 28 is generic.

### ***Reasons why Unity is Lacking***

9. The inventions listed as Groups I-III and the various species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a method for the production of an anti-human antigen receptor comprising the step of selecting a VH chain which is derived from essentially unprimed mature human B lymphocytes.

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Griffiths et al. (US Pat. No. 5,885,793) (see entire document).

Griffiths et al. teach a method for the production of antibodies to human self antigens comprising the step of selecting a VH chain which is derived from essentially unprimed mature human B lymphocytes (see entire document, but especially column 9, and in particular lines 15-31). An anti-human antigen receptor as disclosed in the instant specification includes antibodies to human self antigens, as taught throughout Griffiths et al.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

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10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 26, 2002

PHILLIP GAMBEL  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
TECH CENTER 1600  
3/26/02